

# SAFETY DATA SHEET

According to REACH Regulation (EC) No 1907/2006, as amended by  
UK REACH Regulations SI 2019/758



## Ketamine (5%) Formulation

Version 3.2      Revision Date: 30.09.2023      SDS Number: 9374146-00007      Date of last issue: 04.04.2023  
Date of first issue: 27.08.2021

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### SECTION 1: Identification of the substance/mixture and of the company/undertaking

#### 1.1 Product identifier

Trade name : Ketamine (5%) Formulation

#### 1.2 Relevant identified uses of the substance or mixture and uses advised against

Use of the Sub-stance/Mixture : Veterinary product

Recommended restrictions on use : Not applicable

#### 1.3 Details of the supplier of the safety data sheet

Company : MSD  
Walton Manor, Walton  
MK7 7AJ Milton Keynes - United Kingdom

Telephone : +1-908-740-4000

E-mail address of person responsible for the SDS : EHSDATASTEWARD@msd.com

#### 1.4 Emergency telephone number

+1-908-423-6000

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### SECTION 2: Hazards identification

#### 2.1 Classification of the substance or mixture

**Classification (REGULATION (EC) No 1272/2008) as amended by GB-CLP Regulation, UK SI 2019/720, and UK SI 2020/1567)**

Reproductive toxicity, Category 2      H361d: Suspected of damaging the unborn child.

#### 2.2 Label elements

**Labelling (REGULATION (EC) No 1272/2008) as amended by GB-CLP Regulation, UK SI 2019/720, and UK SI 2020/1567)**

Hazard pictograms :



Signal word : Warning

Hazard statements : H361d Suspected of damaging the unborn child.

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Precautionary statements : **Prevention:**  
P201 Obtain special instructions before use.  
P280 Wear protective gloves/ protective clothing/ eye protection/ face protection.

**Response:**  
P308 + P313 IF exposed or concerned: Get medical advice/ attention.

**Storage:**  
P405 Store locked up.

Hazardous components which must be listed on the label:

Ketamine hydrochloride

### Additional Labelling

The following percentage of the mixture consists of ingredient(s) with unknown hazards to the aquatic environment: 5 %

### 2.3 Other hazards

This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.

## SECTION 3: Composition/information on ingredients

### 3.2 Mixtures

#### Components

Chemical name	CAS-No. EC-No. Index-No. Registration number	Classification	Concentration (% w/w)
Ketamine hydrochloride	1867-66-9 217-484-6	Acute Tox. 4; H302 Skin Irrit. 2; H315 Eye Irrit. 2; H319 Repr. 2; H361d STOT RE 2; H373 (Kidney, Liver, Brain)	>= 3 - < 10

For explanation of abbreviations see section 16.

## SECTION 4: First aid measures

### 4.1 Description of first aid measures

General advice : In the case of accident or if you feel unwell, seek medical advice immediately.  
When symptoms persist or in all cases of doubt seek medical

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advice.

- Protection of first-aiders : First Aid responders should pay attention to self-protection, and use the recommended personal protective equipment when the potential for exposure exists (see section 8).
- If inhaled : If inhaled, remove to fresh air.  
Get medical attention.
- In case of skin contact : In case of contact, immediately flush skin with plenty of water. Remove contaminated clothing and shoes. Get medical attention. Wash clothing before reuse. Thoroughly clean shoes before reuse.
- In case of eye contact : Flush eyes with water as a precaution. Get medical attention if irritation develops and persists.
- If swallowed : If swallowed, DO NOT induce vomiting. Get medical attention. Rinse mouth thoroughly with water.

### 4.2 Most important symptoms and effects, both acute and delayed

- Risks : Suspected of damaging the unborn child.

### 4.3 Indication of any immediate medical attention and special treatment needed

- Treatment : Treat symptomatically and supportively.

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## SECTION 5: Firefighting measures

### 5.1 Extinguishing media

- Suitable extinguishing media : Water spray  
Alcohol-resistant foam  
Carbon dioxide (CO<sub>2</sub>)  
Dry chemical
- Unsuitable extinguishing media : None known.

### 5.2 Special hazards arising from the substance or mixture

- Specific hazards during fire-fighting : Exposure to combustion products may be a hazard to health.
- Hazardous combustion products : Carbon oxides  
Chlorine compounds  
Nitrogen oxides (NO<sub>x</sub>)

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### 5.3 Advice for firefighters

- Special protective equipment for firefighters : In the event of fire, wear self-contained breathing apparatus. Use personal protective equipment.
- Specific extinguishing methods : Use extinguishing measures that are appropriate to local circumstances and the surrounding environment. Use water spray to cool unopened containers. Remove undamaged containers from fire area if it is safe to do so. Evacuate area.
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## SECTION 6: Accidental release measures

### 6.1 Personal precautions, protective equipment and emergency procedures

- Personal precautions : Use personal protective equipment. Follow safe handling advice (see section 7) and personal protective equipment recommendations (see section 8).

### 6.2 Environmental precautions

- Environmental precautions : Avoid release to the environment. Prevent further leakage or spillage if safe to do so. Prevent spreading over a wide area (e.g. by containment or oil barriers). Retain and dispose of contaminated wash water. If spillage enters rivers or watercourses, inform the Environment Agency (emergency telephone number 0800 807060).

### 6.3 Methods and material for containment and cleaning up

- Methods for cleaning up : Soak up with inert absorbent material. For large spills, provide dyking or other appropriate containment to keep material from spreading. If dyked material can be pumped, store recovered material in appropriate container. Clean up remaining materials from spill with suitable absorbent. Local or national regulations may apply to releases and disposal of this material, as well as those materials and items employed in the cleanup of releases. You will need to determine which regulations are applicable. Sections 13 and 15 of this SDS provide information regarding certain local or national requirements.

### 6.4 Reference to other sections

See sections: 7, 8, 11, 12 and 13.

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## SECTION 7: Handling and storage

### 7.1 Precautions for safe handling

- Technical measures : See Engineering measures under EXPOSURE CONTROLS/PERSONAL PROTECTION section.
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- Local/Total ventilation : Use only with adequate ventilation.
- Advice on safe handling : Do not get on skin or clothing.  
Do not breathe mist or vapours.  
Do not swallow.  
Avoid contact with eyes.  
Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure assessment  
Take care to prevent spills, waste and minimize release to the environment.
- Hygiene measures : If exposure to chemical is likely during typical use, provide eye flushing systems and safety showers close to the working place. When using do not eat, drink or smoke. Wash contaminated clothing before re-use.  
The effective operation of a facility should include review of engineering controls, proper personal protective equipment, appropriate degowning and decontamination procedures, industrial hygiene monitoring, medical surveillance and the use of administrative controls.

### 7.2 Conditions for safe storage, including any incompatibilities

- Requirements for storage areas and containers : Keep in properly labelled containers. Store locked up. Store in accordance with the particular national regulations.
- Advice on common storage : Do not store with the following product types:  
Strong oxidizing agents  
Gases

### 7.3 Specific end use(s)

- Specific use(s) : No data available

## SECTION 8: Exposure controls/personal protection

### 8.1 Control parameters

#### Occupational Exposure Limits

Components	CAS-No.	Value type (Form of exposure)	Control parameters	Basis
Ketamine hydrochloride	1867-66-9	TWA	10 µg/m <sup>3</sup> (OEB 3)	Internal
	Further information: Skin			
		Wipe limit	100 µg/100 cm <sup>2</sup>	Internal

### 8.2 Exposure controls

#### Engineering measures

Use appropriate engineering controls and manufacturing technologies to control airborne concentrations (e.g., drip-less quick connections).  
All engineering controls should be implemented by facility design and operated in accordance with GMP principles to protect products, workers, and the environment.

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Containment technologies suitable for controlling compounds are required to control at source and to prevent migration of the compound to uncontrolled areas (e.g., open-face containment devices).

Minimize open handling.

### Personal protective equipment

Eye/face protection	:	Wear safety glasses with side shields or goggles. If the work environment or activity involves dusty conditions, mists or aerosols, wear the appropriate goggles. Wear a faceshield or other full face protection if there is a potential for direct contact to the face with dusts, mists, or aerosols.
Hand protection	:	
Material	:	Chemical-resistant gloves
Remarks	:	Consider double gloving.
Skin and body protection	:	Work uniform or laboratory coat. Additional body garments should be used based upon the task being performed (e.g., sleevelets, apron, gauntlets, disposable suits) to avoid exposed skin surfaces. Use appropriate degowning techniques to remove potentially contaminated clothing.
Respiratory protection	:	If adequate local exhaust ventilation is not available or exposure assessment demonstrates exposures outside the recommended guidelines, use respiratory protection. Equipment should conform to BS EN 143
Filter type	:	Particulates type (P)

## SECTION 9: Physical and chemical properties

### 9.1 Information on basic physical and chemical properties

Appearance	:	liquid
Colour	:	No data available
Odour	:	No data available
Odour Threshold	:	No data available
pH	:	No data available
Melting point/freezing point	:	No data available
Initial boiling point and boiling range	:	No data available
Flash point	:	No data available
Evaporation rate	:	No data available
Flammability (solid, gas)	:	Not applicable
Upper explosion limit / Upper flammability limit	:	No data available
Lower explosion limit / Lower	:	No data available

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flammability limit

Vapour pressure : No data available

Relative vapour density : No data available

Relative density : No data available

Density : No data available

Solubility(ies)

Water solubility : soluble

Partition coefficient: n-octanol/water : Not applicable

Auto-ignition temperature : No data available

Decomposition temperature : No data available

Viscosity

Viscosity, kinematic : No data available

Explosive properties : Not explosive

Oxidizing properties : The substance or mixture is not classified as oxidizing.

### 9.2 Other information

Flammability (liquids) : No data available

Molecular weight : No data available

Particle size : Not applicable

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## SECTION 10: Stability and reactivity

### 10.1 Reactivity

Not classified as a reactivity hazard.

### 10.2 Chemical stability

Stable under normal conditions.

### 10.3 Possibility of hazardous reactions

Hazardous reactions : Can react with strong oxidizing agents.

### 10.4 Conditions to avoid

Conditions to avoid : None known.

### 10.5 Incompatible materials

Materials to avoid : Oxidizing agents

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### 10.6 Hazardous decomposition products

No hazardous decomposition products are known.

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## SECTION 11: Toxicological information

### 11.1 Information on toxicological effects

Information on likely routes of exposure : Inhalation  
Skin contact  
Ingestion  
Eye contact

#### Acute toxicity

Not classified based on available information.

#### Product:

Acute oral toxicity : Acute toxicity estimate: > 2,000 mg/kg  
Method: Calculation method

#### Components:

##### **Ketamine hydrochloride:**

Acute oral toxicity : LD50 (Rat): 447 mg/kg  
LD50 (Mouse): 617 mg/kg

Acute toxicity (other routes of administration) : LD50 (Rat): 59 mg/kg  
Application Route: Intravenous

LD50 (Mouse): 59 mg/kg  
Application Route: Intramuscular

LD50 (Mouse): 356 mg/kg  
Application Route: Intramuscular

LD50 (Guinea pig): 361 mg/kg  
Application Route: Intramuscular

LD50 (Rat): 224 mg/kg  
Application Route: Intraperitoneal

#### **Skin corrosion/irritation**

Not classified based on available information.

#### Components:

##### **Ketamine hydrochloride:**

Species : Rabbit  
Result : irritating

#### **Serious eye damage/eye irritation**

Not classified based on available information.



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### Components:

#### **Ketamine hydrochloride:**

Species : Rabbit  
Result : irritating

#### **Respiratory or skin sensitisation**

##### **Skin sensitisation**

Not classified based on available information.

##### **Respiratory sensitisation**

Not classified based on available information.

##### **Germ cell mutagenicity**

Not classified based on available information.

##### **Carcinogenicity**

Not classified based on available information.

##### **Reproductive toxicity**

Suspected of damaging the unborn child.

### Components:

#### **Ketamine hydrochloride:**

Effects on foetal development : Test Type: Development  
Species: Rat  
Application Route: Intramuscular  
Developmental Toxicity: NOAEL: 120 mg/kg body weight  
Target Organs: Kidney, Liver, Heart  
Result: No teratogenic effects

Test Type: Development  
Species: Rabbit  
Application Route: Intramuscular  
Developmental Toxicity: LOAEL: 20 mg/kg body weight  
Symptoms: Skeletal and visceral variations  
Result: Effects on prenatal and postnatal growth.

Test Type: Development  
Species: Rat  
Application Route: Intramuscular  
Symptoms: Skeletal and visceral variations  
Result: Effects on prenatal and postnatal growth.

Test Type: Development  
Species: Rabbit  
Application Route: Intramuscular  
Developmental Toxicity: LOAEL: 60 mg/kg body weight  
Symptoms: Skeletal and visceral variations  
Result: Effects on prenatal and postnatal growth.

Test Type: Development

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Species: Monkey  
Application Route: Intramuscular  
Target Organs: Brain  
Result: Effects on prenatal and postnatal growth.

Reproductive toxicity - Assessment : Suspected of damaging the unborn child.

### **STOT - single exposure**

Not classified based on available information.

### **STOT - repeated exposure**

Not classified based on available information.

### **Components:**

#### **Ketamine hydrochloride:**

Exposure routes : Skin contact  
Target Organs : Kidney, Liver, Brain  
Assessment : May cause damage to organs through prolonged or repeated exposure.

### **Repeated dose toxicity**

#### **Components:**

#### **Ketamine hydrochloride:**

Species : Mouse  
LOAEL : 30 mg/kg  
Application Route : Intraperitoneal  
Exposure time : 3 Months  
Target Organs : Kidney, Liver, Bladder  
Remarks : Significant toxicity observed in testing

Species : Mouse  
LOAEL : 30 mg/kg  
Application Route : Intraperitoneal  
Exposure time : 6 Months  
Target Organs : Kidney, Liver, Bladder  
Remarks : Significant toxicity observed in testing

Species : Mouse  
LOAEL : 30 mg/kg  
Application Route : Intraperitoneal  
Exposure time : 28 Weeks  
Target Organs : Kidney  
Remarks : Significant toxicity observed in testing

Species : Mouse  
LOAEL : 30 mg/kg  
Application Route : Intraperitoneal  
Exposure time : 30 Days  
Target Organs : Brain, Liver  
Remarks : Significant toxicity observed in testing

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Species	:	Monkey
LOAEL	:	1 mg/kg
Application Route	:	Intraperitoneal
Exposure time	:	6 Months
Target Organs	:	Brain
Remarks	:	Significant toxicity observed in testing

### Aspiration toxicity

Not classified based on available information.

### Experience with human exposure

#### Components:

#### **Ketamine hydrochloride:**

Ingestion : Symptoms: The most common side effects are:, central nervous system effects, hypertension, Dizziness, Headache, Nausea, Drowsiness

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## SECTION 12: Ecological information

### 12.1 Toxicity

#### Components:

#### **Ketamine hydrochloride:**

#### **Ecotoxicology Assessment**

Acute aquatic toxicity : Toxic effects cannot be excluded

Chronic aquatic toxicity : Toxic effects cannot be excluded

### 12.2 Persistence and degradability

No data available

### 12.3 Bioaccumulative potential

#### Components:

#### **Ketamine hydrochloride:**

Partition coefficient: n-octanol/water : log Pow: 2.18

### 12.4 Mobility in soil

No data available

### 12.5 Results of PBT and vPvB assessment

#### Product:

Assessment : This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of

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0.1% or higher.

### 12.6 Endocrine disrupting properties

**Product:**

Assessment : The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

### 12.7 Other adverse effects

No data available

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## SECTION 13: Disposal considerations

### 13.1 Waste treatment methods

Product : Dispose of in accordance with local regulations. According to the European Waste Catalogue, Waste Codes are not product specific, but application specific. Waste codes should be assigned by the user, preferably in discussion with the waste disposal authorities. Do not dispose of waste into sewer.

Contaminated packaging : Empty containers should be taken to an approved waste handling site for recycling or disposal. If not otherwise specified: Dispose of as unused product.

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## SECTION 14: Transport information

### 14.1 UN number

ADN : Not regulated as a dangerous good  
ADR : Not regulated as a dangerous good  
RID : Not regulated as a dangerous good  
IMDG : Not regulated as a dangerous good  
IATA : Not regulated as a dangerous good

### 14.2 UN proper shipping name

ADN : Not regulated as a dangerous good  
ADR : Not regulated as a dangerous good  
RID : Not regulated as a dangerous good  
IMDG : Not regulated as a dangerous good  
IATA : Not regulated as a dangerous good

### 14.3 Transport hazard class(es)

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**ADN** : Not regulated as a dangerous good  
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### 14.4 Packing group

**ADN** : Not regulated as a dangerous good  
**ADR** : Not regulated as a dangerous good  
**RID** : Not regulated as a dangerous good  
**IMDG** : Not regulated as a dangerous good  
**IATA (Cargo)** : Not regulated as a dangerous good  
**IATA (Passenger)** : Not regulated as a dangerous good

### 14.5 Environmental hazards

Not regulated as a dangerous good

### 14.6 Special precautions for user

Not applicable

### 14.7 Transport in bulk according to Annex II of Marpol and the IBC Code

Remarks : Not applicable for product as supplied.

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## SECTION 15: Regulatory information

### 15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture

Relevant EU provisions transposed through retained EU law

UK REACH List of restrictions (Annex 17) : Conditions of restriction for the following entries should be considered:  
Number on list 3  
  
Substance(s) or mixture(s) are listed here according to their appearance in the regulation, irrespective of their use/purpose or the conditions of the restriction. Please refer to the conditions in corresponding Regulation to determine whether an entry is applicable to the placing on the market or not.

UK REACH Candidate list of substances of very high concern (SVHC) for Authorisation : Not applicable

The Persistent Organic Pollutants Regulations (retained Regulation (EU) 2019/1021 as amended for Great Britain) : Not applicable

Regulation (EC) No 1005/2009 on substances that de- : Not applicable

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plete the ozone layer

UK REACH List of substances subject to authorisation (Annex XIV) : Not applicable

GB Export and import of hazardous chemicals - Prior Informed Consent (PIC) Regulation : Not applicable

Control of Major Accident Hazards Regulations 2015 (COMAH) : Not applicable

### Other regulations:

Take note of The Management of Health and Safety at Work Regulations 1999 (requirements relating to new and expectant mothers at work contained in Regulation 16 to 18) and of the Pregnant Workers Directive 92/85/EEC.

### The components of this product are reported in the following inventories:

AICS : not determined

DSL : not determined

IECSC : not determined

## 15.2 Chemical safety assessment

A Chemical Safety Assessment has not been carried out.

## SECTION 16: Other information

Other information : Items where changes have been made to the previous version are highlighted in the body of this document by two vertical lines.

### Full text of H-Statements

H302 : Harmful if swallowed.

H315 : Causes skin irritation.

H319 : Causes serious eye irritation.

H361d : Suspected of damaging the unborn child.

H373 : May cause damage to organs through prolonged or repeated exposure in contact with skin.

### Full text of other abbreviations

Acute Tox. : Acute toxicity

Eye Irrit. : Eye irritation

Repr. : Reproductive toxicity

Skin Irrit. : Skin irritation

STOT RE : Specific target organ toxicity - repeated exposure

ADN - European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways; ADR - Agreement concerning the International Carriage of Dangerous Goods by Road; AIIC - Australian Inventory of Industrial Chemicals; ASTM - American Society for the Testing of Materials; bw - Body weight; CLP - Classification Labelling Packaging Regulation; Regulation (EC) No 1272/2008; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECHA - European Chemicals Agency; EC-Number - European Community number; ECx - Concentration associated with x% response; ELx - Loading rate associated with x% response; EmS - Emergen-

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cy Schedule; ENCS - Existing and New Chemical Substances (Japan); ErCx - Concentration associated with x% growth rate response; GHS - Globally Harmonized System; GLP - Good Laboratory Practice; IARC - International Agency for Research on Cancer; IATA - International Air Transport Association; IBC - International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk; IC50 - Half maximal inhibitory concentration; ICAO - International Civil Aviation Organization; IECSC - Inventory of Existing Chemical Substances in China; IMDG - International Maritime Dangerous Goods; IMO - International Maritime Organization; ISHL - Industrial Safety and Health Law (Japan); ISO - International Organisation for Standardization; KECI - Korea Existing Chemicals Inventory; LC50 - Lethal Concentration to 50 % of a test population; LD50 - Lethal Dose to 50% of a test population (Median Lethal Dose); MARPOL - International Convention for the Prevention of Pollution from Ships; n.o.s. - Not Otherwise Specified; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NZIoC - New Zealand Inventory of Chemicals; OECD - Organization for Economic Co-operation and Development; OPPTS - Office of Chemical Safety and Pollution Prevention; PBT - Persistent, Bioaccumulative and Toxic substance; PICCS - Philippines Inventory of Chemicals and Chemical Substances; (Q)SAR - (Quantitative) Structure Activity Relationship; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; RID - Regulations concerning the International Carriage of Dangerous Goods by Rail; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; SVHC - Substance of very high concern; TCSI - Taiwan Chemical Substance Inventory; TECI - Thailand Existing Chemicals Inventory; TSCA - Toxic Substances Control Act (United States); UN - United Nations; UNRTDG - United Nations Recommendations on the Transport of Dangerous Goods; vPvB - Very Persistent and Very Bioaccumulative

### Further information

Sources of key data used to compile the Safety Data Sheet : Internal technical data, data from raw material SDSs, OECD eChem Portal search results and European Chemicals Agency, <http://echa.europa.eu/>

### Classification of the mixture:

Repr. 2

H361d

### Classification procedure:

Calculation method

The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and shall not be considered a warranty or quality specification of any type. The information provided relates only to the specific material identified at the top of this SDS and may not be valid when the SDS material is used in combination with any other materials or in any process, unless specified in the text. Material users should review the information and recommendations in the specific context of their intended manner of handling, use, processing and storage, including an assessment of the appropriateness of the SDS material in the user's end product, if applicable.

GB / EN